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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,079	04/22/2005	Jamila Najib	BJS-3665-129	9192

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EXAMINER	
BARKER, MICHAEL P	
ART UNIT	**PAPER NUMBER**
1626	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,079	NAJIB ET AL.	
	Examiner	Art Unit	
	Michael P. Barker	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-103* is/are pending in the application.

4a) Of the above claim(s) *nonelected subj. matter of 69-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69, 70, 74, 77, 80, 85, 86, 87, 91-93, 96, 97, and 99-103 (in part)* is/are rejected.

7)☒ Claim(s) *69-103* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 JAN 05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 69-103 are pending in this Application.

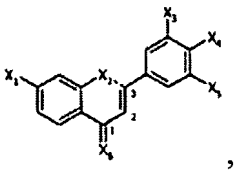
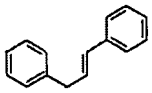
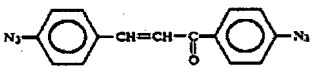
Information Disclosure Statement

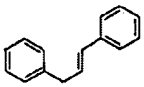
The information disclosure statement (IDS) submitted on 5 January 2005 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS was considered by the Examiner. Please refer to Applicant's copy of PTO-1449, submitted herewith.

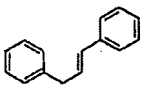
Response to Restriction Requirement

Applicant elected Group III in the response filed 28 March 2007. The Examiner then sent a Miscellaneous Action requesting Applicant elect an invention for search and examination purposes, filed 29 May 2007. Applicant then filed a response electing a species for search and examination purposes, field 29 June 2007. The Examiner's Miscellaneous Action was sent in error. Applicant was not required to elect a species and had fulfilled the request for an election of a group in the response sent 28 March 2007.

Nonetheless, Applicant's election of the species, 1-[4-methylthiophenyl]-3-[3,5-dimethyl-4-carboxydimethylmethyloxyphenyl]prop-2-en-1-one *with traverse*, in the reply filed 29 June 2007, is acknowledged, and falls within previously elected Group III. Applicant's traversal comes on the ground that the Examiner did not adequately demonstrate a lack of unity because the cited reference did not demonstrate a lack of a special technical feature. This traversal is not found persuasive.

Applicant's invention is drawn to compounds of formula (I),  , in which X_2 may or may not be bound to carbon 3 of the propene chain, meaning the core structure may or may not contain a bicyclic ring system. Therefore, taking into account the variables, the only core structure which can be said to be present in each and every claim is the 'arbitrary structural moiety' (28 Mar. 2007 Response, p. 1) contained in the 5,326,670 patent,  , at col. 3, line 40,  . Applicant is correct in pointing out this structure is does not anticipate nor render obvious Applicant's invention. However, pointing out this core structure was in no way meant as a rejection of Applicant's claims. Rather, this structure contains Applicant's core structural feature found in each and every of Applicant's claims,

 , which is present even when X_2 is bound to carbon 3 of the propene chain.

Because the technical feature common to each of the instant claims,  , is not a special technical feature, i.e. this core structure is disclosed in one or more prior art references, the technical feature does not make a contribution over the prior art. Instead, the contribution Applicant's invention makes over the prior art is found in the arrangement and selection of the substituents. As it stands, the Restriction Requirement merely goes to show Applicant's claims are drawn to more than one grouping of structures, each of which, in itself, could be considered a

separate invention, whether by special technical feature, by common classification, by common chemical knowledge, or even by search burden. Because of the reasons set forth in the Restriction Requirement, the restriction is deemed proper and is hereby maintained. Applicant's elected species falls within Group III of the Restriction Requirement field 28 March 2007, which has been examined in its entirety.

Scope of Subject Matter Searched

Group III: **Claims 69, 70, 74, 77, 80, 85, 86, 87, 91-93, 96, 97,** and **98-103** (in part), drawn to compounds of Formula (I), wherein $\mathbf{X_6}$ is oxygen, $\mathbf{X_2}$ is **not** bound to carbon 3 of the propene chain, and the remaining substituents are as defined, as well as the methods of preparing and using these compounds and compositions.

Scope of Subject Matter Not Searched

The remaining subject matter which was not outlined in the scope of the elected subject matter listed above is considered nonelected subject matter and is withdrawn from further consideration. This subject matter is patentably distinct from the elected subject matter, such that the nonelected subject matter would not anticipate nor render the elected subject matter obvious. Applicant reserves the right to file divisional applications on the nonelected subject matter.

Claim Rejections - Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 69, 70, 74, 77, 80, 85, 86, 87, 91-93, 96, 97, and **99-103** (in part) are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over **Claims 1-10** of copending Application No. 11/493,040 and **Claims 38-68** of copending Application No. 10/520,078. These are provisional double patenting rejections since the conflicting Applications have not yet been patented. Please note, **Claims 69, 70, 74, 77, 80, 85, 86, 87, 91-93, 96, 97,** and **99-103** are rejected as they relate to the elected Group III. The scope of the search was not expanded beyond Group III; therefore, the entirety of **Claims 69-103** have not been rejected.

- **Claims 1-8** of the '040 Application disclose compositions whose scope overlaps with the pharmaceutical compositions disclosed in **Claims 99-102** of the instant Application.
    - The difference between **Claims 1-8** of the '040 Application and Claims 99-102 of the instant Application is slight. **Claims 1-8** overlap **Claims 99-102** in scope. **Claim 1** of the '040 Application discloses an identical scope to **Claim 99** of the instant Application. **Claims 5** and **6** of the '040 Application disclose species which anticipate **Claims 99-102** of the instant Application. The uses of the compositions of the '040 Application and instant Application also overlap, despite the fact that the '040 Application discloses a slightly broader scope of disorders than does the instant Application.

- Likewise, **Claims 38-67** of the '078 Application disclose compositions whose scope overlaps with the pharmaceutical compositions disclosed in **Claims 99-102** of the instant Application to such an extent that **Claims 99-102** are not patentably distinct from **Claims 38-67** of the '078 Application.

- **Claim 10** of the '040 Application discloses numerous species which anticipate the Markush language disclosed in **Claims 69, 70, 74, 77, 80, 85, 86, 87, 91-93** of the instant Application.

- **Claim 68** of the '078 Application and **Claim 9** of the '040 Application each discloses a method of treatment and/or prophylaxis of disorders related to PPAR pathways, which

overlaps significantly in scope with **Claim 103** of the instant Application, which also discloses a method of treatment and/or prophylaxis of disorders related to PPAR pathways.

- **Claims 61**, **62**, and **66** of the '078 Application disclose at least one composition containing a compound disclosed in the instant Application at **Claims 96** and **97**, namely 1-[4-bromophenyl]-3-[3,5-dimethyl-4-carboxydimethylmethyloxyphenyl]prop-2-en-1-one. Applicant is likely in a better position to determine exactly which species overlap from the two copending Applications versus the instant Application. For the purposes of an obviousness-double patenting rejection, it is sufficient that there is at least one overlapping species.

One skilled in the art would have found the instantly claimed compounds, compositions, and methods of use prima facie obvious over the '040 and '078 Applications because the instantly claimed compounds, compositions, and methods of use fall within or parallel the scope delineated by the claims of the '040 and '078 Applications. The motivation to make the claimed compounds and compositions derives from the expectation that structurally similar or identical compounds and compositions would possess similar activity (i.e. pharmacological use related to PPAR pathways and cerebral vascular-related disorders). Although, the conflicting claims are not precisely identical, they are not patentably distinct from each other because Applicant's instantly claimed invention is disclosed within the scope of the co-pending Applications.

According to MPEP 804 I (B)(1), if a provisional obviousness type double patenting rejection is the only outstanding rejection, it may be issued in a junior case, where other terminal disclaimers have been filed in co-pending applications. MPEP 804 I (B)(1) states:

1. Nonstatutory Double Patenting Rejections

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

Claim Rejections - 35 USC § 112 ¶1

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 100-103 are rejected under 35 U.S.C. 112, first paragraph. The Specification enables treating (not prophylaxis of) cerebral ischemia and hemorrhagic stroke but does not enable the treatment or prophylaxis of every cerebrovascular pathology, prophylaxis of cerebral ischemia, prophylaxis of hemorrhagic stroke, nor the treatment or prophylaxis of every cerebrovascular disease. Therefore, the Specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims.

Many factors are considered when determining whether the evidence is sufficient to satisfy the enablement requirement and whether any necessary experimentation is "undue." In re Wands, 858 F.2d 731, 742 (Fed. Cir. 1988).

These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Id. at 738.

Claim 100 is drawn to a pharmaceutical composition 'in a form for the treatment or prophylaxis of cerebrovascular pathology.' This claim encompasses both treating and preventing every known cerebrovascular pathology.

Claim 101 is drawn to a pharmaceutical composition 'in a form for the treatment or prophylaxis of a cerebral ischemia.' This claim encompasses preventing cerebral ischemia.

Claim 102 is drawn to a pharmaceutical composition 'in a form for the treatment or prophylaxis of a hemorrhagic stroke.' This claim encompasses preventing hemorrhagic stroke.

Claim 103 is drawn to a 'method of treatment and/or prophylaxis of cerebrovascular diseases'. This claim encompasses the treatment and prevention of every known cerebrovascular disease.

The level of ordinary skill in the art is extremely high, with many of the pharmaceutical sciences possessing advanced degrees. Despite the high level of ordinary skill required in pharmacology, Applicant's Specification does not enable **Claims 100-103**. There is no absolute predictability even in view of the seemingly high level of skill in the art.

The state of the prior art is such that screening *in vitro* and *in vivo* is necessary to determine which compounds exhibit desired pharmacological activities, in this case treatment and prophylaxis of every cerebrovascular pathology and disease. The existence of these screening obstacles and nature of the unpredictability of pharmacological arts would prevent one of ordinary skill in the art from accepting a preventive regimen on its face and from accepting the prevention and treatment of every cerebrovascular pathology or disease.

The Applicant provides evidence of the claimed compounds' antioxidant properties, PPAR agonist properties, neuroprotection properties, and anti-inflammatory properties in various *in vitro* and *in vivo* models.

Despite the great deal of evidence presented by Applicant, the state of the prior art does not currently accept that a class of compounds is capable of treating every cerebrovascular pathology or disease nor capable of preventing every cerebrovascular pathology or disease, preventing cerebral ischemia, or preventing hemorrhagic stroke. Even Applicant's own cited

bibliography tends to show evidence of the treatment of specific cerebrovascular diseases rather than their prevention. Because of the aforementioned reasoning, **Claims 100-103** are rejected, and one suggestion to overcome this rejection is to delete **Claims 100** and **103** and delete the word, "prophylaxis" from **Claims 101** and **102**.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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